DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 3, 2015

BIONIME CORPORATION
C/O FENG-YU LEE
PRINCIPAL CONSULTANT
29222 RANCHO VIEJO ROAD, SUITE 218
SAN JUAN CAPISTRANO CA 92675

Re: K143387
Trade/Device Name: GE Blood Glucose Monitoring System 333
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: May 4, 2015
Received: May 6, 2015

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
GE Blood Glucose Monitoring System 333

Indications for Use *(Describe)*
The GE Blood Glucose Monitoring System 333 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE Blood Glucose Monitoring System 333 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 333 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE Blood Glucose Monitoring System 333 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE Blood Glucose Test Strips 333 are for use with the GE Blood Glucose Meter 333 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k143387

1. Submitter's Identification:

BIONIME CORPORRATION
NO 100, Sec. 2, Daqing St., South Dist., 40242 Taichung City, Taiwan

Phone Number: 886-4-23692388
FAX Number: 886-4-22617568

c/o IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
Phone Number: 1-949-218-0929
Fax Number: 1-949-218-0928

Date Summary Prepared: May 29, 2015

2. Name of the Device:
GE Blood Glucose Monitoring System 333

3. Common or Usual Name: Glucose test system

Product Code	Classification	Regulation Section	Panel
NBW; System, Test, Blood Glucose, Over-the-Counter	Class II	21 CFR 862.1345	Clinical Chemistry 75
CGA; Glucose Oxidase, Glucose	Class II	21 CFR 862.1345	Clinical Chemistry 75

4. Device Description:

4.1 The GE Blood Glucose Monitoring System 333 consists of the following devices: GE Blood Glucose Meter 333, GE Blood Glucose Test Strip 333, and Rightest Control Solution GC550. The GE333 Blood Glucose Meter and GE Blood Glucose Test Strips 333 are manufactured by BIONIME Corporation. The GE Blood Glucose Meter 333, when used with the GE Blood Glucose Test Strips 333, quantitatively measures glucose in fresh capillary whole blood. The performance of the GE Blood Glucose Monitoring System 333 is verified by the Rightest Control Solution GC550.

The Rightest Control Solution GC550 has been previously been cleared (k092052) and is being repackage for use with the GE Blood Glucose Monitoring System 333.

5. Intended Use:

The GE Blood Glucose Monitoring System 333 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE Blood Glucose Monitoring System 333 is intended to be used by a single person and should not be shared.

The GE Blood Glucose Monitoring System 333 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE Blood Glucose Monitoring System 333 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE Blood Glucose Test Strips 333 are for use with the GE Blood Glucose Meter 333 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

6. Predicate Device Information:

The GE Blood Glucose Monitoring System 333 is substantially equivalent to the Rightest Blood Glucose Monitoring System noted below.

Name: Rightest Blood Glucose Monitoring System GM550
Device Company: Bionime Corporation
510(K) Number: K092052
Name: Rightest Blood Glucose Monitoring System GM550
Name: Rightest Blood Glucose Test Strips GS550
Name: Rightest Blood Glucose Control Solution GC550
Device Company: Bionime Corporation

7. Comparison to Predicate Devices:

Specification Comparison

Item	New Device	Predicate Device
	GE Blood Glucose Monitoring System 333	Rightest GM550
Similarities		
Measuring Range	20-600 mg/dL	
Sample	Capillary whole blood (finger, palm and forearm)	
Measurement Technology	Oxidase Electrochemical Sensor	
Strip Reagent	1.Glucose Oxidase (GOD) 14.8% 2.Potassium ferricyanide 39.5% 3.Non-reactive ingredients 45.7%	
The unit of measurement data	Fix on mg/dL	
Shelf Life after opened vial	3 months	
Test Time	5 seconds	
Coding	Auto coding	
Operating Temperature Range	50 ~104 ℉ (10 ~ 40℃)	
Operating Relative Humidity Range	10 ~ 90%	
Test Strip Storage Conditions	39 ~86 ℉ (4 ~ 30℃), ＜90% relative humidity	
Meter Storage Conditions	14 ~140 ℉ (-10 ~ 60℃)	
Monitor	LCD display	
Memory Capacity	500 blood glucose test results with date and time	
Control solution	2 levels (Level 2 and 4, GC550)	
Differences		
Interference	Ascorbic acid ≧ 5 mg/dL Cholesterol ≧ 600 mg/dL	Uric acid ≧ 10mg/dL L-Dopa ≧ 3mg/dL

		Dopamine ≧ 2mg/dL Ascorbic acid ≧ 5 mg/dL
Intended Use	In vitro diagnostic use - OTC	In vitro diagnostic use - OTC and POC
Hematocrit Range	20-60%	30-60%
Minimum Sample Volume	0.75 μL	1 μL
Backlight	No	Yes
Power Supply	Two 1.5V (AAA) batteries	Two CR2032 batteries
Meter Dimension	85 mm × 57 mm × 22.5 mm	90.6 mm x 46 mm x 16.5 mm
Meter Weight	81.0 ± 5 g with batteries	53.0 ± 5 g with batteries
Battery Life	About 800 tests	About 1000 tests
LCD display area	39 mm × 39.5 mm	47 mm × 33.5 mm
Wireless module	Bluetooth 4.0 (Low energy)	No

8. Technology Characteristics:

GE Blood Glucose Test Strip 333 paired with GE Blood Glucose Meter 333 that utilizes electrical characteristic technology for measuring the glucose level in human blood. A relatively small drop of blood (minimum requirement of only 0.75 μL) is placed on the disposable GE Test Strip 333 coated with Glucose Oxidase which interacts with the GE Blood Glucose Meter 333. Within 5 seconds after testing, the blood glucose level is indicated on the meter's digital display screen.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Rightest Blood Glucose Meter GM232 and Rightest Blood Glucose Test Strips GS550 were used for testing, which are identical to GE Blood Glucose Meter 333 and GE Blood Glucose Test Strips 333, respectively, with the exception of trade name.

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the GE Blood Glucose Monitoring System 333. The evaluation included precision, linearity, interference, sample volume and hematocrit.

The following studies and evaluations were either performed internally by professional personnel in Bionime or by third party, performed by qualified personnel, with proper calibrated/maintained equipment and under properly-controlled environmental conditions. All of the evaluated performances passed and meet the acceptance criteria set forth in the study protocol.

Linearity

The linearity study evaluated detection range using 3 lots of blood glucose test strips. Venous blood samples spiked to 15 levels of glucose concentrations were used, ranging from low to high level (0 to 604 mg/dL), and evaluated compared to reference method YSI 2300 analyzer.

The tested glucose concentration ranged from 0 to 604 mg/dL. Analysis of results indicated linear regression between device and reference method shows mean slopes above 0.9912 and R^2 values above 0.999. The results support the claim that glucose assay is linear from 20-600 mg/dL – identical to prior 510k cleared claims. The linearity study report is attached for your review.

Precision:

Based on the requirements, the precision study evaluated repeatability – conducted over 10 days at 5 glucose concentrations, and intermediate precision – conducted over 10 days at 3 glucose concentrations. 10 meters (3 models), 3 lots of test strips were used; 1500 test strips were used for repeatability evaluation and 900 test strips were used for intermediate precision evaluation. The venous blood sample results were compared against reference method YSI 2300 Analyzer.

The repeatability evaluation and intermediate precision evaluation results demonstrate that repeatability and intermediate precision falls within the acceptance criteria. The precision study report is attached for your review.

Sample Volume

The sample volume study evaluated sample volume using 3 lots of blood glucose test strips. Venous blood at 3 glucose concentration levels and at 9 sample volumes (ranging from 0.60 to 3.0 μL) was used.

The sample volume study results demonstrate that when sample volumes were less than 0.60μL, meter displayed error message (Er4). At all other sample volumes (greater than 0.65 μL), the results were within the accepted criteria of ±10% bias compared to reference. Thus, the minimum sample volume is 0.75 μL.

Interference Study

Based on the requirements and standards of CLSI: EP7-A2, the interference study evaluated interference substances using 3 lots of test strips at 2 glucose concentration levels of venous blood samples, and 19 interference substances.

According to study results, ascorbic acid (≥ 5 mg/dL), cholesterol (600 mg/dL), and uric acid (≥ 10 mg/dL) indicate percentage of interference over ±10% bias in high glucose concentration. This may lead to inaccurate test results, and is stated in the limitations section of the test strip package insert. The remaining 16 interference substances are within the criteria for normal and high glucose concentrations.

Hematocrit Study

The Hematocrit Study evaluated hematocrit levels using 3 lots of blood glucose test strips (HCT range 20-60%) at 6 glucose concentration levels of venous blood samples, tested in 5 replicates. The results were compared against reference method YSI 2300 Analyzer.

The obtained study results indicate that the stability compared to the reference method during various HCT ranges were all within the criteria of ±15% of reference value. The acceptable HCT range is 20-60%.

10. Discussion of Clinical Test Performed:

System Accuracy Study:
System accuracy and precision was evaluated to 1) determine if subject device meets criteria and EGA, and 2) asses clinical performance of measuring glucose in capillary whole blood obtained from fingertip, palm, and/or forearm. The study was performed by comparing blood glucose values measured on subject device with values measured on comparative meter (Roche ACCU-CHEK Performa), with YSI 2300 Plus Glucose Analyzer used as a reference.

A total of 103 patients were participated. The study result demonstrates that the accuracy of subject device met the acceptance criteria, and there was no significant difference in slope, intercept, and correlation coefficient between the comparative meter or reference lab instrument.

User Performance Study:
A User Performance Evaluation Study was performed to demonstrate that lay users could obtain accurate results using the subject device. The study was performed using capillary whole blood from fingertip, palm and forearm sample sites by evaluating total of 160 laypersons in multiple sites. The study result shows substantial equivalence to predicate device used in finger, palm and forearm position.

11. Conclusions:

Results of non-clinical and clinical performance evaluation of the GE Blood Glucose Monitoring System 333 demonstrate that the device is substantially equivalent to the predicate device, Rightest Blood Glucose Monitoring System GM550.